

anticipated the above cited claims. It was asserted that the polymers were alpha amino acids having the general formula as that disclosed by applicants, where Leucine or Phenylalanine were used as starting amino acids for esterification. It was further asserted that the reference's biodegradable polymers were used in the medical field such as controlled drug delivery and that deformability and conformability to surface application were inherent for the particular polymer. (Office action, page 3). Applicants respectfully disagree and traverse this rejection

Applicants believe that claims 1-3,6,7 and 18 should be held patentable over the disclosure of Saotome *et al* because "A claim is anticipated only if each and every claim element as set forth in the claim is found either expressly or inherently described in a single prior art reference." MPEP § 2131. Thus, to anticipate a claim, the reference must teach every element of the claim. *Id.* Here, the Applicants disclose a polymer blend of two or more, poly(ester amide) polymers (PEA)s whereas the cited reference describes only one type of polymer with either Glycine, Leucine or Phenylalanine as starting amino acids. Therefore, claim 1 should be held allowable because it is not anticipated by the reference. Likewise, claims 2-3 and 18 that depend on claim 1 should also be allowable.

Furthermore, while Saotome *et al.* may arguably indicate that biodegradable polymers have applications in medical fields such as controlled drug delivery, the reference does not specifically teach solid articles or sheets, or the deformability of the particular articles composed of the claimed blended polymers. Therefore, claim 6 directed to deformable sheets is allowable over this reference, as is claim 7 that depends on claim 6. Applicants respectfully request that the rejection of claims 1-3, 6,7 and 18 be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 4,5,8-17,19-23 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Saotome *et al.* in view of Katsarava *et al.*, Patent, Republic of Georgia, (1997) (Office Action, page 3).

Applicants respectfully disagree and traverse this rejection. It was admitted in the Office Action that Saotome *et al.* do not teach the ratio of Phe-PEA to Leu-PEA (claims 4, 5), the particular bioactive agents (claims 8 and 19), the chymotrypsin enzyme adsorbed to the surface of the polymer (claims 9-12, 20-23) and the method of treating the wound (claims 13-17).

However, it was asserted that it is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. It was asserted that the ratio of Phe-PEA to Leu-PEA instantly claimed in claims 5 and 6 were not critical, absent evidence showing unexpected and superior results.

Moreover, it was asserted that Katsarava *et al.* teach a film wound dressing that can be used to accelerate wound healing (the method of claims 13-17), comprising antiseptic and biodegradable material based on PEA with prolonged action. Further, it was asserted that the polymer was impregnated with bacteriophages and proteolytic enzyme  $\alpha$ -chymotrypsin immobilized at the surface (claims 8-12,19-23). It was thus asserted that it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a wound dressing motivated by the teaching of Katsarava *et al.* that the wound dressing comprising the PEA polymer, bacteriophage and chymotrypsin achieve the elimination of toxic component, the attachment of the biodegradation properties and the simplification of the preparation processing, with reasonable expectation of success of the delivered dressing in treating different kinds of wounds and ulcers. (Office Action, page 5).

As conceded in the Office Action, the invention as claimed is not literally anticipated by the prior art reference because the current invention teaches a blend of the PEA polymers unlike the prior art. Applicants respectfully submit that the cited claims are not obvious because Saotome *et al.* do not provide any reason to blend two or more polymers. Absent motivation to modify the reference, the present invention cannot be held to be obvious. MPEP § 2143.01. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1998).

Furthermore, Applicants have discovered that the detrimental characteristics inherent in each class of PEAs can be overcome by blending them. For example, PEAs based on L-Phenylalanine do not possess sufficient plasticity for use as wound coverings. See specification on page 8. Further, the films prepared from L-Leucine PEAs are very sticky, adhering to themselves, and inconvenient to work with. See specification on page 8. Additionally, L-Leucine based PEAs immobilize enzymes poorly. See specification on page 8. However, polymeric blends prepared from approximately 70% of L-Phenylalanine based PEAs and 30% of

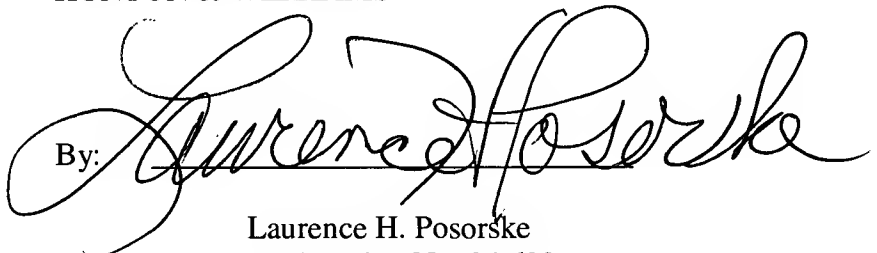
L-Leucine based PEAs showed: good plasticity (necessary to cover wounds tightly), lack of self adhesion and ability to immobilize enzymes. See specification on page 8. In addition, enzyme degradation studies showed the enhanced release of bacteriophage from the polymer. See data on Table 1 in the Example on pages 13-16 of the application. Therefore, in view of these considerations, Applicants respectfully submit that claims 4,5,8-17 and 19-23 should all be held allowable.

**REQUEST FOR ALLOWANCE**

Applicants earnestly solicit reconsideration of the application in view of these remarks. Applicants respectfully submit that in view of the above remarks, this application is in condition for allowance and respectfully request an early notification of allowance. If any further action is necessary to place this application in condition for allowance, Applicants would appreciate a telephone call to the undersigned counsel to resolve such issues in a expeditious and effective manner.

Respectfully submitted,  
HUNTON & WILLIAMS

Dated: July 22, 2003

By:   
Laurence H. Posorske  
Registration No. 34,698

Hunton & Williams LLP  
Intellectual Property Department  
1900 K Street, N.W., Suite 1200  
Washington, DC 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)

202 419 2080